



SYBRON DENTAL SPECIALTIES

FEB 04 2002

Section III - 510(k) Summary of Safety and Effectiveness

KOI 3895

Submitter:

Sybron Dental Specialties, Inc.  
1717 W. Collins Avenue  
Orange, California 92867  
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Colleen Boswell - Contact Person

Date Summary Prepared: November 2001

Device Name:

- Trade Name – *TempFil*
- Common Name – Temporary Dental Restorative Material
- Classification Name – Temporary Crown and Bridge Resin, per 21 CFR § 872.3770

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *TempFil F - 2*

Device Description:

TempFil is a light cured single component temporary filling material designed for fabrication of provisional inlays and onlays. TempFil contains a resin base, which provides a sculptable viscosity with non-sticky placement. Available in syringe and unidose delivery systems; TempFil sets to a permanent elastic phase which allows for easy removal even in the presence of preparation undercuts.

Intended Use of the Device:

The intended use of *TempFil* is for temporary filling of inlay and onlay preparations, implant screw and endodontic access openings, and for the emergency replacement of lost fillings.

Substantial Equivalence:

*TempFil* is substantially equivalent to other legally marketed devices in the United States. *TempFil* functions in a manner similar to and is intended for the same use as the original *TempFil F - 2* formulation that was manufactured by Kerr Corporation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 04 2002

Ms. Colleen Boswell  
Director, Corporate Compliance  
Sybron Dental Specialties, Incorporated  
1717 West Collins Avenue  
Orange, California 92867

Re: K013895  
Trade/Device Name: TempFil  
Regulation Number: 872.3770  
Regulation Name: Temporary Dental Restorative Material  
Regulatory Class: II  
Product Code: EBG  
Dated: November 20, 2001  
Received: November 23, 2001

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

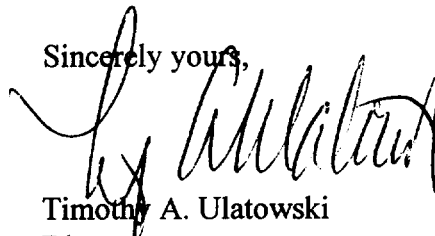
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Section I

Indications for Use Statement

Ver/3 - 4/24/96

Applicant: Kerr Dental Materials Center

510(k) Number (if known): K013895

Device Name: TempFil

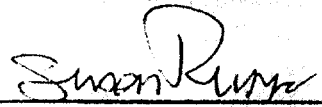
Indications For Use:

*TempFil* is a light-cured, single component temporary filling material intended to be used for filling of inlay and onlay preparations, implant screw and endodontic access openings, and for the emergency replacement of lost fillings.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)  
(Optional Format 1-2)

  
Division Sign-Off  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K013895